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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------|-------------------------------|--------------------------|---------------------|------------------|
| 10/588,272 | 08/04/2006 | Mauro Ajani | 622-96 | 7152 |
| 23117 NIXON & VAN | 7590 03/22/201 NDERHYE, PC | EXAMINER | | |
| 901 NORTH G | LEBE ROAD, 11TH F | WHEELER, THURMAN MICHAEL | | |
| ARLINGTON, VA 22203 | | | ART UNIT | PAPER NUMBER |
| | | | 1619 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/22/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|--|--|--|--|--|
| | 10/588,272 | AJANI ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Thurman Wheeler | 1619 | | | | |
| The MAILING DATE of this communication app | ears on the cover sheet with the c | orrespondence address | | | | |
| Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>04 Au</u> | iaust 2006 | | | | | |
| | action is non-final. | | | | | |
| · <u> </u> | ·— | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | , | | | | | |
| 4)⊠ Claim(s) <u>23-44</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) 23-44 are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine | r | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correcti | | | | | | |
| 11) The oath or declaration is objected to by the Ex | , , , , | • | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| <u> </u> | priority under 35 LLS C & 110(a) | a-(d) or (f) | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| 1. ☐ Certified copies of the priority documents have been received. | | | | | | |
| Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | ate | | | | |
| Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 5) Notice of Informal P 6) Other: | atent Application | | | | |

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DETAILED ACTION

Claims 23-44 are pending in instant application

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 23-33, drawn to an oral pharmaceutical or dietary composition containing at least one short-chain fatty acid or salt, ester and/or amide thereof, in combination with a complex sugar and/or dietary fibre.

Group II. Claims 34-44, drawn to method for the treatment of intestinal disorders, inflammatory disorders, and pathological conditions of the intestinal mucous membrane and for the preventive or limiting treatment of intestinal neoplasia which comprises the administration of a pharmaceutical or dietary composition comprising a short-chain fatty acid in

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combination with a soluble dietary fibre in which the complex sugar and/or dietary fibre is selected from inulin, pectin, dextrin, maltodextrin or derivatives thereof.

- 2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." Moreover, as stated in PCT Rule 13.2, "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."
- 3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Groups I-II is a pharmaceutical or dietary composition comprising a short-chain

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fatty acid in combination with a complex sugar and/or dietary fibre. As disclosed in WO 02/02102 (Bird), the pharmaceutical or dietary composition comprising a short-chain fatty acid in combination with a complex sugar and/or dietary fibre is not novel. Bird teaches a pharmaceutical or dietary composition comprising a short chain fatty acid, such as butyrate (p.5, line 25), where the carrier is a complex sugar, such as inulin and pectin (p.13, lns.12-13). Also, Bird teaches that the carrier can be a natural dietary fibre (p.1, line 18). As such, Group I does not share a special technical feature over the prior art. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-II is broken.

4. The examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and the product and use claims are subsequently found allowable, withdrawn method and use claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected method or use invention must require all the limitations of an allowable product claim for that method or use invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method and use claims will be withdrawn, and the rejoined method and use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims, method and use claims may be maintained. Withdrawn method or use claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the method and use claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Contact Information

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thurman Wheeler whose telephone number is (571)270-1307. The examiner can normally be reached on Monday-Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tracy Vivlemore/ Primary Examiner, Art Unit 1635